

Variations on the Peer Review Theme

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Prof. Guston has ably summarized the essentials concerning regulatory peer review. This note addresses a few small issues that have recently arisen.

Regulatory peer review provides scientific advice, but science advice includes more than peer review. Guston noted this difference, but it has become more significant recently with the invention of what EPA calls "peer consultation."¹ The Agency distinguishes "consultation" from "review" largely on the basis of status in the process of developing regulatory documents. In practice, the distinction may best be understood as the difference between reviewing early and final draft versions of documents. Peer review typically concerns regulatory documents — usually risk or policy analyses or components of such analyses — that are in a final draft stage. They frequently represent nearly settled thinking on the scientific issues involved. Consultation typically concerns such documents that are settled enough to permit review, but in which the analysis is still in flux.

"Science advice" includes both of these, and can also refer to consideration of processes, methods, approaches, *etc.*, that are not described in regulatory documents. We note that a favorable external peer review has increasingly come to represent a stamp of approval on agency positions, and thus something not necessarily desirable (to policy makers) to seek while positions are still evolving. Members of the Science Advisory Board have long noted that their work can be of greater use to the Agency if their opinions are sought early in the process of policy formation, rather than late, and asked to be so consulted. Peer consultation helps satisfy this desire while avoiding the risk of receiving an unfavorable review of a final Agency position.

The dual purposes of regulatory peer review tempt agencies to perform *faux* (cosmetic) peer reviews. As Guston notes, the ultimate purposes of regulatory peer review differ from those of reviews for publication and for granting agencies. Publication and grant peer reviews are intended to reject the unfit, to identify the minority of manuscripts or grant applications that will be published or funded. (To be accurate, these peer reviews usually result in each document being given a rank-ordered recommendation, e.g., "Definitely publish," "Publish, with revisions," "Consider publishing after revisions, if space is available," "Not suitable for publication.") Typically, the major research granting agencies fund fewer than one in five applications; the manuscript acceptance rate for journals varies, but seldom do half of those submitted see publication in the first journal to which they are submitted.

¹ See the accompanying memo from Don Barnes that describes the SAB usage of these terms.

Regulatory peer review and science advice share with these others a quality-control purpose, although this is almost never expressed as acceptance or rejection of a document *in toto*. The usual response consists of a few general comments on the document as a whole, followed by detailed comments (editorial as well as substantive) on individual passages or sections of the document. It is now almost always the case that regulatory science documents include at least a competent review of the relevant literature, and often an excellent one. So there is almost always something for reviewers to praise and accept. More likely to garner critical commentary are key assumptions and the reasoning used to justify them, and inferences drawn from the scientific observations. Failure to identify key assumptions and / or inferences will today almost always engender strong criticism from a peer review, and may occasion rejection of the document. Yet sometimes these key assumptions are subtle, or require sophisticated scientific knowledge to understand. Having people who possess such knowledge part of the review process becomes very important to its utility.

Peer reviews can go awry for a variety of reasons. One way is absence of particular scientific or technical expertise: those setting up the panel fail to include people with critical knowledge and understanding. Another way is a panel that is not representative in its societal (nonscientific) values; such a group can bias the review, one way or another. A third is inadequate framing of the questions asked or issues raised. The current controversies over regulatory peer review occur because of these possibilities.

Policy makers learned very early on the political value of being able to claim peer-review approval of the analyses on which their decisions are based. Thus arose, as night follows day, the phenomenon of cosmetic peer review, *i.e.*, one set up only to approve an analysis — or to reject it, depending on the aims of those organizing the review. Each of the three sources of misadventure noted above can be manipulated by those so inclined, and we can assume that each has been so manipulated one time or another.